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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,452	01/12/2006	Christina Ammann	112701-703	8957

29157 7590 06/26/2009

K&L Gates LLP
P.O. Box 1135
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EXAMINER	
GWARTNEY, ELIZABETH A	

ART UNIT	PAPER NUMBER
1794	

NOTIFICATION DATE	DELIVERY MODE
06/26/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No.	Applicant(s)	
	10/564,452	AMMANN ET AL.	
	Examiner	Art Unit	
	Elizabeth Gwartney	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5 and 8-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5 and 8-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/01/2009 has been entered.

2. Claims 6-7 have been cancelled. Claims 1-2, 5, and 8-15 are pending.

3. The previous claim objections and rejections under 35 USC §112, 1st paragraph have been withdrawn in light of the amendment filed 06/01/2009.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-2, 5 and 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spivey-Krobath et al. (WO 02/39834) in view of Brassart et al. (US 6,489,310).

Regarding claims 1-2 and 5 Spivey-Krobath et al. disclose a liquid or powdered reconstitutable nutritional composition (Abstract, p.5/L35- p.6/L3, p.8/L14-18) comprising a 7.0g or 10.5g protein/100ml composition, a source of digestible carbohydrates, and a source of dietary fiber, having an energy density of 1.6 kcal/ml and dietary fiber in an amount of 4 g. to about 50 g per 300 g of the composition (Abstract, p.3/L15-17, p.5/L5, p.10/Table 1). Spivey-Krobath et al. also disclose a composition wherein the source of fiber comprises 70% by weight fructooligasaccharide (i.e. oligosaccharide) and 30% by weight inulin (i.e. soluble fiber (p.10/Table 1) or a combination of fructooligasaccharide (i.e. soluble non-starch polysaccharide) and acacia gum (i.e. soluble non-starch polysaccharide) (p.5/L5-6).

While modified Spivey-Krobath et al. disclose a nutritional composition with 7g or 10.5g protein/100 ml, the reference does not explicitly disclose about 4.5 to about 6g protein/100ml.

Given that the present claims require about 4.5 to about 6g protein/100 ml, since "about 4.5 and about 6.5g protein/100ml" allows for concentrations slightly about 6g and slightly below

4.5, it is clear that the ranges disclosed by Spivey-Krobath et al., i.e. 7g protein/100 ml, overlap with those presently claimed. In the alternative, it is apparent that the instantly claimed amount of protein, i.e. about 4.5 to about 6g protein/100ml, and that taught by Spivey-Krobath et al., i.e. 7 and 10.5g protein/100 ml, are so close to each other that the fact pattern is similar to the one in *In re Woodruff*, 919 F.2d 1575, USPQ2d 1934 (Fed. Cir. 1990) or *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed.Cir. 1985) where despite a "slight" difference in the ranges the court held that such a difference did not "render the claims patentable" or, alternatively, that "a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough so that one skilled in the art would have expected them to have the same properties"(*see* MPEP 2144.05 – I. Overlap of Ranges). In this case, one skilled in the art would expect that a nutritional composition comprising about 6g protein/100 ml would exhibit the same properties as one comprising 7g protein/100 ml.

Further, Spivey-Krobath et al. does not explicitly disclose a source of fiber comprising the recited ratios including pea outer fiber (i.e. insoluble fiber).

Brassart et al. teach an enteral composition which contains a protein source, a lipid source, a carbohydrate source and a fiber blend (Abstract). Brassart et al. teach that the fiber blend comprises 5-30% inulin (soluble non-starch polysaccharide), 10-40% fructo-oligosaccharides (i.e. oligosaccharide) and 20-50% pea outer fiber (i.e. non-soluble polysaccharide) (C4/L40-44). Brassart et al. teach that enteral compositions containing a balance of soluble and insoluble dietary fiber are less viscous and can be used for tube feeding (C1/L66-

C2/L3). Further, enteral compositions containing the right balance of soluble to insoluble fibers are more stable (C1/L66-C2/L3).

Spivey-Krobath et al. and Brassart et al. are combinable because they are concerned with the same field of endeavor, namely, nutritional compositions. It would have been obvious to one of ordinary skill in the art at the time of the invention to have included a fiber blend including both soluble and insoluble fiber, as taught by Brassart et al, in the nutritional composition of Spivey-Krobath et al. for the purpose of producing a composition that is not to viscous for tube feeding and has increased stability.

With regards to acacia gum, given that Spivey-Krobath disclose the use of soluble fiber including both inulin and acacia gum (p.5/L5-6, p.10/Table 1), it would have been obvious to one of ordinary skill in the art at the time of the invention to have used acacia gum as the soluble fiber in the fiber blend of modified Spivey-Krobath et al. because doing so would amount to nothing more than the use of a known soluble fiber source for its intended use in a known environment to accomplish entirely expected results.

Given that modified Spivey-Krobath et al. disclose a nutritional composition identical to that presently claimed, it is clear that the composition would inherently possess the recited viscosity.

Regarding claim 8, modified Spivey-Krobath et al. disclose all of the claim limitations as set forth above and that the composition comprises a source of lipids (p.7/L8-14, p.10/Table 1).

Regarding claim 9, Spivey-Krobath et al. disclose all of the claim limitations as set forth above. Given that modified Spivey-Krobath et al. disclose a nutritional composition identical to

that presently claimed, since lactose is not disclosed, it is clear that the composition would inherently be clinically free of lactose.

Regarding claims 10-12 and 14-15, Spivey-Krobath also disclose administering an effective amount of a powdered or liquid reconstitutable nutritional composition (Abstract, p.5/L35- p.6/L3, p.8/L14-18) 7.0g or 10.5g protein/100ml composition, a source of digestible carbohydrates, and a source of dietary fiber, having an energy density of 1.6 kcal/ml and dietary fiber in an amount of 4 g. to about 50 g per 300 g of the composition (Abstract, p.3/L15-17, p.5/L5, p.10/Table 1). Spivey-Krobath et al. also disclose a composition wherein the source of fiber comprises 70% by weight fructooligasaccharide (i.e. oligosaccharide) and 30% by weight inulin (i.e. soluble fiber (p.10/Table 1) or a combination of fructooligasaccharide (i.e. soluble non-starch polysaccharide) and acacia gum (i.e. soluble non-starch polysaccharide) (p.5/L5-6).

While modified Spivey-Krobath et al. disclose a nutritional composition with 7g or 10.5g protein/100 ml, the reference does not explicitly disclose about 4.5 to about 6g protein/100ml.

Given that the present claims require about 4.5 to about 6g protein/100 ml, since "about 4.5 and about 6.5g protein/100ml" allows for concentrations slightly about 6g and slightly below 4.5, it is clear that the ranges disclosed by Spivey-Krobath et al., i.e. 7g protein/100 ml, overlap with those presently claimed. In the alternative, it is apparent that the instantly claimed amount of protein, i.e. about 4.5 to about 6g protein/100ml, and that taught by Spivey-Krobath et al., i.e. 7 and 10.5g protein/100 ml, are so close to each other that the fact pattern is similar to the one in *In re Woodruff*, 919 F.2d 1575, USPQ2d 1934 (Fed. Cir. 1990) or *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed.Cir. 1985) where despite a "slight" difference in the ranges the court held that such a difference did not "render the claims

patentable" or, alternatively, that "a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough so that one skilled in the art would have expected them to have the same properties"(*see* MPEP 2144.05 – I. Overlap of Ranges). In this case, one skilled in the art would expect that a nutritional composition comprising about 6g protein/100 ml would exhibit the same properties as one comprising 7g protein/100 ml.

Further, Spivey-Krobath et al. does not explicitly disclose a source of fiber comprising the recited ratios including pea outer fiber (i.e. insoluble fiber).

Brassart et al. teach an enteral composition which contains a protein source, a lipid source, a carbohydrate source and a fiber blend (Abstract). Brassart et al. teach that the fiber blend comprises 5-30% inulin (soluble non-starch polysaccharide), 10-40% fructo-oligosaccharides (i.e. oligosaccharide) and 20-50% pea outer fiber (i.e. non-soluble polysaccharide) (C4/L40-44). Brassart et al. teach that enteral compositions containing a balance of soluble and insoluble dietary fiber are less viscous and can be used for tube feeding (C1/L66-C2/L3). Further, enteral compositions containing the right balance of soluble to insoluble fibers are more stable (C1/L66-C2/L3).

Spivey-Krobath et al. and Brassart et al. are combinable because they are concerned with the same field of endeavor, namely, nutritional compositions. It would have been obvious to one of ordinary skill in the art at the time of the invention to have included a fiber blend including both soluble and insoluble fiber, as taught by Brassart et al, in the nutritional composition of Spivey-Krobath et al. for the purpose of producing a composition that is not to viscous for tube feeding and has increased stability.

With regards to acacia gum, given that Spivey-Krobath disclose the use of soluble fiber including both inulin and acacia gum (p.5/L5-6, p.10/Table 1), it would have been obvious to one of ordinary skill in the art at the time of the invention to have used acacia gum as the soluble fiber in the fiber blend of modified Spivey-Krobath et al. because doing so would amount to nothing more than the use of a known soluble fiber source for its intended use in a known environment to accomplish entirely expected results.

Regarding the intended use of the method, statements in the preamble reciting the purpose or intended use of the claimed invention which do not result in a manipulative difference between the claimed invention and the prior art do not limit the claim and do not distinguish over the prior art process. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963); *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) and cases cited therein, as it has been held that the recitation of a new intended use for an old product does not make a claim to that old product patentable. *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997). See also MPEP § 2111.02 and § 2112 - § 2112.02.

Further, given that modified Spivey-Krobath et al. disclose method as presently claimed, it is clear that such method would intrinsically improve the digest tract and bowel function of a patient, inherently enhance mucosal barrier function in a patient, inherently promote gut health or comfort in an elderly patient, inherently maintain or restore a well-balanced gut flora, and inherently enhance mucosal function in a human individual.

Regarding claim 13, Spivey-Krobath et al. disclose a method for preparing a nutritional composition comprising the steps of mixing a liquid or powdered reconstitutable nutritional composition 7.0g or 10.5g protein/100ml composition, a source of digestible carbohydrates, and a source of dietary fiber, having an energy density of 1.6 kcal/ml and dietary fiber in an amount of 4 g. to about 50 g per 300 g of the composition (Abstract, p.3/L15-17, p.5/L5, p.10/Table 1). Spivey-Krobath et al. also disclose a composition wherein the source of fiber comprises 70% by weight fructooligasaccharide (i.e. oligosaccharide) and 30% by weight inulin (i.e. soluble fiber (p.10/Table 1) or a combination of fructooligasaccharide (i.e. soluble non-starch polysaccharide) and acacia gum (i.e. soluble non-starch polysaccharide) (p.5/L5-6).

While modified Spivey-Krobath et al. disclose a nutritional composition with 7g or 10.5g protein/100 ml, the reference does not explicitly disclose about 4.5 to about 6g protein/100ml.

Given that the present claims require about 4.5 to about 6g protein/100 ml, since "about 4.5 and about 6.5g protein/100ml" allows for concentrations slightly about 6g and slightly below 4.5, it is clear that the ranges disclosed by Spivey-Krobath et al., i.e. 7g protein/100 ml, overlap with those presently claimed. In the alternative, it is apparent that the instantly claimed amount of protein, i.e. about 4.5 to about 6g protein/100ml, and that taught by Spivey-Krobath et al., i.e. 7 and 10.5g protein/100 ml, are so close to each other that the fact pattern is similar to the one in *In re Woodruff*, 919 F.2d 1575, USPQ2d 1934 (Fed. Cir. 1990) or *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed.Cir. 1985) where despite a "slight" difference in the ranges the court held that such a difference did not "render the claims patentable" or, alternatively, that "a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough so that one skilled in the art

would have expected them to have the same properties"(*see* MPEP 2144.05 – I. Overlap of Ranges). In this case, one skilled in the art would expect that a nutritional composition comprising about 6g protein/100 ml would exhibit the same properties as one comprising 7g protein/100 ml.

Further, Spivey-Krobath et al. does not explicitly disclose a source of fiber comprising the recited ratios including pea outer fiber (i.e. insoluble fiber).

Brassart et al. teach an enteral composition which contains a protein source, a lipid source, a carbohydrate source and a fiber blend (Abstract). Brassart et al. teach that the fiber blend comprises 5-30% inulin (soluble non-starch polysaccharide), 10-40% fructo-oligosaccharides (i.e. oligosaccharide) and 20-50% pea outer fiber (i.e. non-soluble polysaccharide) (C4/L40-44). Brassart et al. teach that enteral compositions containing a balance of soluble and insoluble dietary fiber are less viscous and can be used for tube feeding (C1/L66-C2/L3). Further, enteral compositions containing the right balance of soluble to insoluble fibers are more stable (C1/L66-C2/L3).

Spivey-Krobath et al. and Brassart et al. are combinable because they are concerned with the same field of endeavor, namely, nutritional compositions. It would have been obvious to one of ordinary skill in the art at the time of the invention to have included a fiber blend including both soluble and insoluble fiber, as taught by Brassart et al, in the nutritional composition of Spivey-Krobath et al. for the purpose of producing a composition that is not to viscous for tube feeding and has increased stability.

With regards to acacia gum, given that Spivey-Krobath disclose the use of soluble fiber including both inulin and acacia gum (p.5/L5-6, p.10/Table 1), it would have been obvious to

one of ordinary skill in the art at the time of the invention to have used acacia gum as the soluble fiber in the fiber blend of modified Spivey-Krobath et al. because doing so would amount to nothing more than the use of a known soluble fiber source for its intended use in a known environment to accomplish entirely expected results.

Response to Arguments

8. Applicant's arguments filed 06/01/2009 have been fully considered but they are not persuasive.

Applicants argue that Spivey-Krobath et al. fails to disclose or suggest a nutritional composition comprising about 4.5 to about 6g protein/100ml composition or the presently claimed viscosity. Further, Applicants argue that because Spivey-Krobath does not disclose the "identical" composition as presently claimed, i.e. compositions having about 4.5 to about 6g protein/100ml composition, the composition of modified Spivey-Krobath do not necessarily provide for compositions having a viscosity of 30 to 80 mPas.

Applicants' argument is not persuasive. The present claims require ***about*** 4.5 to ***about*** 6g protein/100ml composition. Since, the term "***about***" allows for concentrations slightly above 6g and slightly below 4.5g, it is clear that the protein content disclosed by Spivey-Krobath et al., i.e. 7g protein/100ml composition, overlaps with those presently claimed. In the alternative, it is apparent that the instantly claimed amount of protein, i.e. about 4.5 to about 6g protein/100ml, and that taught by Spivey-Krobath et al., i.e. 7 and 10.5g protein/100 ml, are so close to each other that the fact pattern is similar to the one in *In re Woodruff*, 919 F.2d 1575, USPQ2d 1934 (Fed. Cir. 1990) or *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773

(Fed.Cir. 1985) where despite a "slight" difference in the ranges the court held that such a difference did not "render the claims patentable" or, alternatively, that "a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough so that one skilled in the art would have expected them to have the same properties"(*see* MPEP 2144.05 – I. Overlap of Ranges). In this case, one skilled in the art would expect that a nutritional composition comprising about 6g protein/100 ml would exhibit similar properties to one comprising 7g protein/100 ml.

Further, while modified Spivey-Krobath et al. discloses a composition identical to that presently claimed including a protein content that overlaps with the claimed content of about 4.5 to about 6g protein/100ml composition, it necessarily follows that the composition would have a viscosity of 30 to 80 mPas. Given the slight difference between about 6g and 7g protein, one of ordinary skill in the art would not expect a composition comprising 7g protein/100 ml to exhibit a much different viscosity than about comprising about 6g protein/100 ml. Since the viscosity range presently claimed is fairly broad, given modified Spivey-Krobath et al. disclose a composition identical to that presently claimed, including protein content (see preceding argument), it is clear that the composition of modified Spivey-Krobath et al. would inherently display a viscosity in the range presently claimed.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Gwartney whose telephone number is (571) 270-3874. The examiner can normally be reached on Monday - Friday;7:30AM - 3:30PM EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. G./
Examiner, Art Unit 1794

/KEITH D. HENDRICKS/
Supervisory Patent Examiner, Art Unit 1794